

**DECLARATION**

I, Jeffrey C. Barfield of Alpenrosenstr. 3, 82377 Penzberg, Germany, do hereby declare that I am conversant with the English and German languages and that I am a competent translator thereof.

I verify that the attached English translation is a true and correct translation of the Annex of the Official Letter of October 17, 2003 in connection with the international patent application PCT/EP03/00111.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: June 28, 2004

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Jeffrey C. Barfield

**Ad Item V:**

**Justified determination in accordance with Article 66.2(a)(ii) with respect to novelty, inventive step and industrial application; documents and declarations to support this determination.**

1. Reference is made to the following documents:

D1: WO 99 55594 A

D2: WO 01 00498 A

D3: JP 11 240553 A (& PATENT ABSTRACTS OF JAPAN vol. 1999, no. 14, December 22, 1999 (1999-12-22))

D4: EP-A-0 602 019

2. Document D1 discloses (the references in brackets refer to Fig. 3 of this document) a valve for the application of drops of a liquid (6) stored in a container (1) comprising a take-up body (2b) which has a discharge passage (7) for the liquid, with a single elastically deformable membrane (3) being arranged in the intake element (2b) and sealingly closing the discharge passage (7).

The valve described in D1 thus includes all technical features of the subject matter of claim 1, which is therefore not new.

Furthermore, such a valve is also disclosed in D2 (Fig. 1), D3 (Fig. 2) and D4 (Fig. 10).

3. Dependent claims 2 to 14 and 16 to 18 do not include any features which, in combination with the features of any claim on which they depend, satisfy the requirements of the PCT with respect to novelty. The reasons for this are as follows:
- D1 discloses the feature combinations of claims 2, 4-7, 9, 13 and 16-18.
  - D2 discloses the feature combinations of claims 3, 10-12 and 14; and
  - D4 discloses the feature combinations of claim 8.

4. Dependent claim 15 does not include any features which, in combination with the features of any claim on which it depends, satisfy the requirements of the PCT with respect to novelty. The reasons for this are that D3 discloses a valve from which the subject matter of claim 15 only differs in that a sterile filter is provided. Providing such a valve with a sterile filter is, however, a usual measure to avoid the contamination of the contents of the container, see D4. The person skilled in the art would therefore consider it a usual procedure to install a sterile filter in the valve in accordance with D3.

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I verify that the attached English translation is a true and correct translation of the German language patent application with the international publication number WO 03/057587 A1 and the international file reference PCT/EP03/00111.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: June 28, 2004

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Jeffrey C. Barfield